

Docket No.: 022290.0159PTUS

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Gauthier Pouliquen et al.

Application No.: 10/580023

Filed: May 19, 2006

For: PHAR

PHARMACEUTICAL FORMULATIONS FOR THE PROLONGED RELEASE OF ACTIVE PRINCIPLE(S) AND THEIR THERAPEUTIC APPLICATIONS Confirmation No.: N/A

Art Unit: N/A

Examiner: Not Yet Assigned

## **INFORMATION DISCLOSURE STATEMENT (IDS)**

Customer Window U.S. Patent and Trademark Office Randolph Building 401 Dulany Street Alexandria, Virginia 22314

Dear Sir.

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

A concise explanation of relevance of the items listed on form PTO/SB/08 is given for only non-English language listed items. FR 02 07008, FR 02 09670, FR 03 50190 and FR 03 50641 relate to novel water-soluble amphiphilic polyamino acids comprising aspartic units and/or glutamic

09/26/2006 GFREY1

00000071 10580023

01 FC:1806

180.00 OP

Application No.: 10/580023 Docket No.: 022290.0159PTUS

units, in which at least some of these units carry hydrophobic grafts. FR-A-2801226 relates to methods of obtaining a polyamino acid or the alpha type.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-2228, under Order No. 022290.0159PTUS. A duplicate copy of this paper is enclosed.

Dated: September 21, 2006

Respectfully submitted,

Lacy L. Kolo

Registration No.: 55,340

PATTON BOGGS LLP

8484 Westpark Drive, 9th Floor

McLean, Virginia 22102

(703) 744-8000

(703) 744-8001 (Fax)

Attorney for Applicant

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/B/PTO Application Number 10/580023 INFORMATION DISCLOSURE Filing Date May 19, 2006 STATEMENT BY APPLICANT Gauthier Pouliquen First Named Inventor Art Unit N/A (Use as many sheets as necessary) Examiner Name Not Yet Assigned 022290.0159PTUS 1 Sheet 1 of Attomey Docket Number

			U.S. PA	TENT DOCUMENTS	
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	No.1	Number-Kind Code <sup>2</sup> ( if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
	AA*	US-6,143,314	11-07-2000	Chandrashekar et al.	
	AB*	US-6,500,448	12-31-2002	Johnson et al.	
	AC*	US-20030133980-A1	07-17-2003	Costantino et al.	
	AD*	US-5,399,331	03-21-1995	Loughrey et al.	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code³-Number⁴-Kind Code⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	ВА	WO-9918142	04-15-1999	Rathi et al.		1		
	ВВ	WO-0018821	04-06-2000	Rathi et al.		1		
	ВС	WO-9811874	03-26-1998	Lindell, Katarina		1		
	BD	WO-0030618	06-02-2000	Huille et al.		1		
	BE	FR-0207008	12-12-2003	Ping et al.				
	BF	FR-0209670	02-06-2004	Angot et al.				
	BG	FR-0350190	12-03-2004	Angot et al.				
	ВН	FR-0350641	10/03/2003	Soula et al.				
	ВІ	FR-2801226	05/25/2001	Touraud et al.				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	CA	FORSSEN et al., <u>Cancer Res.</u> 43: 546 (1983)				
	CB	REGALADO, J. et al., Macromolecules 32: 8580 (1999)				
	CC	FULLER et al., <u>Biopolymers</u> 15: 1869 (1976)				
	CD	KRICHELDORF, H.R., Alpha-Amino Acid N-Carboxy Anhydrides and Related Heterocycles Springer Verlag (1987)				
	CE	TOMIDA et al., Polymer 38: 4733-36 (1997)				
	CF	GUPTA, P.K. et al., Injectable Drug Development Interpharm Press, Denver, Colorado (1999)				
	CG	GAO J. Y., et al., Anal. Chem. 69: 2945 (1997)				
	СН	DEKKER, M., Surfactant Science Series Vol. 22, Surfactant Solutions, Ed. R. Zana, Chap. 3 (1984)				

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner	Date
Examine:	
Signature	Considered
Signature	Considered

IAP15 Rec'd PCT/PTO 21 SE

## PTO/SB/21 (09-04) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Application Number 10/580023 Filing Date TRANSMITTAL May 19, 2006 First Named Inventor **FORM** Gauthier Pouliquen Art Unit N/A (to be used for all correspondence after initial filing) **Examiner Name** Not Yet Assigned Attorney Docket Number 022290.0159PTUS Total Number of Pages in This Submission ENCLOSURES (Check all that apply) After Allowance Communication x | Fee Transmittal Form Drawing(s) Appeal Communication to Board of Fee Attached Licensing-related Papers Appeals and Interferences Appeal Communication to TC Amendment/Reply Petition (Appeal Notice, Brief, Reply Brief) Petition to Convert to a After Final Proprietary Information **Provisional Application** Power of Attorney, Revocation Affidavits/declaration(s) Status Letter Change of Correspondence Address Other Enclosure(s) (please Extension of Time Request Terminal Disclaimer Identify below): **Express Abandonment Request** Request for Refund Information Disclosure Statement CD, Number of CD(s) Certified Copy of Priority Landscape Table on CD Document(s) Reply to Missing Parts/ Remarks Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name

PATTON BOGGS LLP Signature Printed name -Lacy L. Kolo Date Reg. No. 55,340 September 21, 2006

PTO/SB/17 (07-06)

Complete the Paperwork Reduction Act of 1995, no person are required to respond to a collection of international contents of the Consolidated Applicant Consolidated Appropriations Act 2005 (FR. 4918)   FEE TRANSMITTAL   For FY 2005   Filting Date   May 19, 2006   Filting Da	לא טו		. 4005		U.S. Paten		ed for use through ark Office; U.S. DE		
FEE TRANSMITTAL FOR FY 2005  Applicant claims small entity status. See 37 CFR 1.27  TOTAL AMOUNT OF PAYMENT (\$) 180.00  METHOD OF PAYMENT (check all that apply)  Check X Credit Card Money Order None Other (please identify):  Deposit Account Deposit Account Number 50-2228 Deposit Account Name Patton Boggs LLP For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)  FEE CALCULATION  1. BASIC FILING, SEARCH, AND EXAMINATION FEES FILING FEES SEARCH FEES SEARCH FEES Small Entity Application Type Fee (\$)	Under the Pa			uirea to	respond to a collectic	Com	plete if Knov	vn	5 CONTO NUMBE
For FY 2005  Applicant claims small entity status. See 37 CFR 1.27  TOTAL AMOUNT OF PAYMENT (\$) 180.00 Attorney Docket No. 022290.0159PTUS  METHOD OF PAYMENT (check all that apply)  Check X Credit Card Money Order None Other (please identify):  Deposit Account Number 50-2228 Deposit Account Name. Patton Boggs LLP  For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)  Charge fee(s) indicated below X Charge fee(s) Fee(	Fees pursuant to			4818).	Application Nur	mber	10/580,023		
For FY 2005  Applicant claims small entity status. See 37 CFR 1.27  TOTAL AMOUNT OF PAYMENT (\$) 180.00 Attorney Docket No. 022290.0159PTUS  METHOD OF PAYMENT (check all that apply)  Check X Credit Card Money Order None Other (please identify):  Deposit Account Number 50-2228 Deposit Account Name. Patton Boggs LLP  For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)  Charge fee(s) indicated below X Charge fee(s) Fee(	FFI	FTRANS	MITTAL		Filing Date	ī	May 19, 2006		
Applicant claims small entity status. See 37 CFR 1.27  TOTAL AMOUNT OF PAYMENT (\$) 180.00 Attorney Docket No. 022290.0159PTUS  METHOD OF PAYMENT (check all that apply)  Check X Credit Card Money Order None Other (please identify):  Deposit Account Deposit Account Number, 50-2228 Deposit Account Name: Patton Boggs LLP  For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)  Charge fee(s) indicated below Charge fee(s) indicated below, except for the filing fee Status of Statu	'-			First Named Inv	ventor (	Gauthier Pouliquen			
METHOD OF PAYMENT (check all that apply)		FOFFY Z	005	Examiner Name	, 1	Not Yet Assig	ned		
METHOD OF PAYMENT (check all that apply)	Applica	nt claims small entity sta	tus. See 37 CFR 1.27		Art Unit	1	N/A		
Check X Credit Card Money Order None Other (please identify):    Deposit Account   Deposit Account Number, 50-2228   Deposit Account Name   Patton Boggs LLP	TOTAL AMOU	INT OF PAYMENT	(\$) 180.00		Attorney Docket	No.	022290.0159	PTUS	
Deposit Account Deposit Account Number: 50-2228 Deposit Account Name: Patton Boggs LLP  For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)  Charge fee(s) indicated below Credit any overpayments Credit	METHOD O	F PAYMENT (check	all that apply)						
For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)  Charge fee(s) indicated below Charge fee(s) indicated below Account of the filling fee  Charge any additional fee(s) or underpayment of the filling fee and for filling fee and for the filling fee and for the filling fee and for the filling fee and for filling fee and for the filling fee and for filling fee and for the filling fee and for filling fee and fo	Check	x Credit Card	Money Order	Nor	ne Other	(please ident	ify):		
Charge fee(s) indicated below  Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17  FEE CALCULATION  1. BASIC FILING, SEARCH, AND EXAMINATION FEES FILING FEES Small Entity Application Type Fee(s)	Deposit A	ccount Deposit Account	Number: 50-2228 De	eposit Acc	ount Name:	1	Patton Boggs	LLP	
Charge fee(s) indicated below  Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17  FEE CALCULATION  1. BASIC FILING, SEARCH, AND EXAMINATION FEES FILING FEES Small Entity Application Type Fee(s)	For the	above-identified dep	osit account, the Dir	ector is	hereby authorize	ed to: (chec	k all that apply	)	
FEE CALCULATION									the filing fee
FEE CALCULATION				nent of	x Credit	any overpa	ayments		
The specification Type			1.16 and 1.17						<del></del>
Filing FEES			VAMINATION EEE	9	<del></del>				<del></del>
Application Type	I. BASIC FILIP	•			ARCH FEES	EXAMIN	IATION FEES	3	
Utility	i		Small Entity		Small Entity		<b>Small Entity</b>		D . I . I . (A)
Design								Fees	Paid (\$)
Plant	1 '								
Reissue	_								<del></del>
Provisional 200 100 0 0 0 0 0 0 0 0 0 0 2. EXCESS CLAIM FEES									
2. EXCESS CLAIM FEES Fee Description Each claim over 20 (including Reissues) Each independent claim over 3 (including Reissues)  Multiple dependent claims  Total Claims Extra Claims Fee (\$) HP = highest number of total claims paid for, if greater than 20.  Indep. Claims Extra Claims Fee (\$) HP = highest number of independent claims paid for, if greater than 3.  3. APPLICATION SIZE FEE If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).  Total Sheets Extra Sheets Number of each additional 50 or fraction thereof (round up to a whole number) x  Fee Paid (\$)  Submitted BY  Signature  Registration No. (Attorney/Agent) 55,340 Telephone (703) 744-8000	Reissue	300	150	500					
Fee Description Each claim over 20 (including Reissues) Each independent claim over 3 (including Reissues)  Multiple dependent claims  Total Claims Extra Claims Fee (\$) Fee Paid (\$)  Multiple Dependent Claims Fee (\$) Fee Paid (\$)  HP = highest number of total claims paid for, if greater than 20.  Indep. Claims Extra Claims Fee (\$) Fee Paid (\$)  HP = highest number of independent claims paid for, if greater than 3.  3. APPLICATION SIZE FEE  If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).  Total Sheets Extra Sheets Number of each additional 50 or fraction thereof Fee (\$) Fee Paid (\$)  Fee Paid (\$)  Fee Paid (\$)  Total Sheets Extra Sheets Number of each additional 50 or fraction thereof Fee (\$) Fee Paid (\$)  Fee Paid (\$)  Fee Paid (\$)  Total Sheets Extra Sheets Number of each additional 50 or fraction thereof Fee (\$) Fee Paid (\$)  Fee (\$)  Fee Paid (\$)  Fee (\$)  Fee Paid	Provisional	200	100	0	0	0	0		
Each claim over 20 (including Reissues)  Each independent claims over 3 (including Reissues)  Multiple dependent claims  Total Claims  Extra Claims  Fee (\$)  Fee Paid (\$)  Multiple Dependent Claims  Fee (\$)  Fee Paid (\$)  Total Claims  Fee (\$)  Fee Paid (\$)  Total Sheets  Extra Sheets  Number of each additional 50 or fraction thereof  Fee (\$)  Fee Paid (\$)  Fee Paid (\$)  Total Sheets  Extra Sheets  Number of each additional 50 or fraction thereof  Fee (\$)  Fee Paid (\$)  Fee Paid (\$)  Fee Paid (\$)  Total Sheets  Extra Sheets  Number of each additional 50 or fraction thereof  Fee (\$)  Fee Paid (\$)  Fees Paid (\$)	2. EXCESS CL	AIM FEES						Eco (\$)	
Each independent claim over 3 (including Reissues)  Multiple dependent claims  Total Claims  Extra Claims  Fee (\$)  Fee Paid (\$)  HP = highest number of total claims paid for, if greater than 20.  Indep. Claims  Extra Claims  Fee (\$)  Fee Paid (\$)  Fee Paid (\$)  HP = highest number of independent claims paid for, if greater than 3.  3. APPLICATION SIZE FEE  If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).  Total Sheets  Extra Sheets  Number of each additional 50 or fraction thereof  -100 = /50									
Multiple dependent claims  Total Claims  Extra Claims  Fee (\$)  Fee Paid (\$)  Multiple Dependent Claims  Fee (\$)  Fee Paid (\$)  HP = highest number of total claims paid for, if greater than 20.  Indep. Claims  Extra Claims  Fee (\$)  Fee Paid (\$)  -3 =		`	•						
Total Claims Extra Claims Fee (\$) Fee Paid (\$) Multiple Dependent Claims  -20 =	_		iuding Keissues)						
HP = highest number of total claims paid for, if greater than 20.  Indep. Claims			Foo (\$)	Foo F	Paid (\$)	Mı	ultiple Depend		
HP = highest number of total claims paid for, if greater than 20.    Indep. Claims	TOTAL CIAITIS				uiu (v)	•			
HP = highest number of independent claims paid for, if greater than 3.  3. APPLICATION SIZE FEE  If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).  Total Sheets	HP = highest nur					_			<u> </u>
HP = highest number of independent claims paid for, if greater than 3.  3. APPLICATION SIZE FEE  If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).  Total Sheets	Indep. Claims			Fee F	Paid (\$)				
3. APPLICATION SIZE FEE  If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).  Total Sheets	LID = high ant gun	- 3		2					
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).  Total Sheets	1 .		s paid for, it greater than	3.				-	
sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).  Total Sheets Extra Sheets Number of each additional 50 or fraction thereof -100 = 150 (round up to a whole number) x = 14. OTHER FEE(S)  Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement 180.00  SUBMITTED BY  Signature Registration No (Attorney/Agent) 55,340 Telephone (703) 744-8000	If the specific	ation and drawings e	exceed 100 sheets of	paper	(excluding electr	ronically fil	led sequence or	r computer	50
- 100 =							inty) for each	additional 5	,,,
4. OTHER FEE(S)  Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement 180.00  SUBMITTED BY  Signature  Registration No. (Attorney/Agent) 55,340 Telephone (703) 744-8000	Total Shee	ts <u>Extra Shee</u>	ts <u>Number o</u>	f each a	dditional 50 or fra	ction thereo	f <u>Fee (\$)</u>	<u>Fee</u>	Paid (\$)
Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement 180.00  SUBMITTED BY  Signature Registration No. (Attorney/Agent) 55,340 Telephone (703) 744-8000		100 =	/50		(round up to a who	ole number)	×	=	
SUBMITTED BY  Signature Registration No. (Attorney/Agent) 55,340 Telephone (703) 744-8000	4. OTHER FEE	(S)						Fees	Paid (\$)
Signature Registration No. (Attorney/Agent) 55,340 Telephone (703) 744-8000	Other (e.g.,	late filing surcharge)	: 1806 Submissio	on of a	n Information D	isclosure	Statement	1	80.00
Signature Registration No. (Attorney/Agent) 55,340 Telephone (703) 744-8000	SUBMITTED BY				•				
		784				55,340	Telephone	(703) 74	14-8000
	Name (Print/Type)	Lacy L. Kolo			, , , , , , , , , , , , , , , , , , ,		Date	Septembe	r 21, 2006

SUBMITTED BY		•			
Signature	724	Registration No. (Attorney/Agent)	55,340	Telephone	(703) 744-8000
Name (Print/Type)	Lacy L. Kolo			Date	September 21, 2006